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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------------|
| 10/593,032 | 09/15/2006 | Minoru Nakao | 47232-5015 | 2824 |
| 55694 7590 12/06/2007 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209 | | | EXAMINER GRASER, JENNIFER E | |
| | | | ART UNIT 1645 | PAPER NUMBER |
| | | | MAIL DATE 12/06/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/593,032 | Applicant(s) NAKAO ET AL. | |
| | Examiner Jennifer E. Graser | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>9/15/06</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the claim does not recite that the peptide to be used as the diagnostic reagent has been 'isolated'. Accordingly, it is unclear if the peptide may be part of a whole cell. It appears that the peptide is meant to be 'isolated'. Appropriate correction is required.

Claims 1, 3 and 4 are vague and indefinite because they recite 'residues 22-65 of residues 20-85 of any one of SEQ ID Nos: 1-4' which is confusing because SEQ ID Nos: 1-4 are only 85 amino acids in length and it is unclear if the residue positions in the SEQ ID Nos: 1-4, e.g., residues 1-85, are being maintained or if they are to be re-numbered starting from residue 22. For example, it is unclear whether this language is meant to encompass residues 22-65 of SEQ ID Nos: 1-4 or if it is meant to encompass residues 41-84 of SEQ ID Nos: 1-4. The latter having the numbering started anew from residue 22. Clarification and/or correction is required.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the claim does not provide a complete

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method. There is no detection step or correlation step in the claimed method. The method should recite that it is testing for infection 'in a subject' and that serum is taken from the subject and contacted with the reagent of claim 1. Then, there should be a detection step and a correlation step. Appropriate correction is required.

Claim 3 is vague and confusing as it should be amended to be in proper method format, e.g., steps of : i) ;

ii) ;

iii);....etc..

A colon should be inserted after 'comprising the steps of'. Additionally, , as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the claim does not provide a complete method. There is no correlation step in the claimed method. Appropriate correction is required.

The wording of claim 3 is also vague and indefinite because the phrase 'subjecting the peptide on the support to react with serum from a subject' in part (ii) is not grammatically correct and confuses the claim. The phrase should be amended to recite 'contacting the peptide on the support with serum from a subject'. The phrase 'subjecting the reactant to react...' in part (iii) is also grammatically incorrect. It appears that perhaps the peptide which is fixed on the support is to be a labeled peptide; however, the claim as written has a probe coming in after the reaction step which is vague and confusing. It is unclear how the probe will react with the antibody/peptide complex after the complex has already been formed. It seems that the peptide would

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be labeled before it came into contact with the antibody in the subject's serum.

Clarification and appropriate correction of the claim is requested.

Claims 1-3 are vague in indefinite because they do not recite what or who is being tested. For example, is one testing for infection of *Taenia solium* and *Taenia saginata* in serum of a subject? Clarification and correction is requested.

Status of Claims:

3. Peptides comprising SEQ ID Nos: 1-5 and peptides containing at least residues 22-65 of 20-85 of SEQ ID Nos: 1-4 are free of the prior art. Additionally, the methods, kits and reagents recited in the instant claims are free of the prior art. Claims 1-4 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

4. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

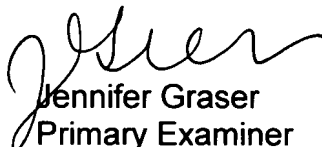
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Shanon Foley, can be reached on (571) 272-0898.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.


Jennifer Graser
Primary Examiner
Art Unit 1645

11/27/07